This document is scheduled to be published in the Federal Register on 08/10/2023 and available online at **federalregister.gov/d/2023-17150**, and on **govinfo.gov**

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-1529]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Voluntary Qualified Importer Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to https://www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review - Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0840. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 240-994-7399, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Voluntary Qualified Importer Program

OMB Control Number 0910-0840--Extension

This information collection supports implementation of FDA's Voluntary Qualified Importer Program (VQIP), a voluntary fee-based program that provides expedited review and import entry of human and animal foods into the United States. Program participants may import products to the United States with greater speed and predictability, avoiding unexpected delays at the point of import entry. Importers interested in applying can start their application (Form FDA 4041) by submitting a notice of intent to participate after setting up an account through the FDA Industry Systems (FIS) website at https://www.access.fda.gov, which includes a VQIP Portal User Guide. To participate, importers must meet eligibility criteria and pay a user fee that covers costs associated with FDA's administration of the program. Consistent with section 743(b)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 379j-31(b)(1)), FDA annually publishes a schedule of fees applicable to VQIP in the *Federal Register*.

Respondents to the information collection are persons that bring food, or cause food to be brought, from a foreign country into the customs territory of the United States (section 806 of the FD&C Act (21 U.S.C. 384b)) as a VQIP importer. A VQIP importer can be located outside the United States. Persons who may be a VQIP importer include the manufacturer, owner, consignee, and importer of record of a food, provided that the importer can meet all the criteria for participation.

To assist respondents with the information collection, we developed the guidance document entitled "FDA's Voluntary Qualified Importer Program" (issued November 2016, updated July 2023 to change the Paperwork Reduction Act burden statement address), available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-fdas-voluntary-qualified-importer-program. The guidance document is prepared in a question-and-answer format and discusses eligibility criteria; includes instruction for completing a VQIP application; explains conditions that may result in revocation of participation as well as criteria for reinstatement; and communicates benefits VQIP importers can expect to receive

under the program. The guidance also discusses preparation of the "Quality Assurance Program (QAP)," a compilation of written policies and procedures used to ensure adequate control over the safety and security of foods being imported. The guidance document was developed and issued consistent with FDA good guidance practice regulations in 21 CFR 10.115, which provides for public comment at any time.

In the *Federal Register* of May 11, 2023 (88 FR 30315), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden[1]

Reporting Using FIS VQIP Portal/Form FDA 4041	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Initial VQIP application	5	1	5	180	900
Application Renewals--subsequent year	6	1	6	20	120
Requests for reinstatement	2	1	2	10	20
Total					1,040

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Table 2.--Estimated Annual Recordkeeping Burden[1]

VQIP Participant Records Consistent with Implementing Guidance	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Quality Assurance Program (QAP) preparation	5	1	5	160	800
QAP maintenance and updates	6	1	6	16	96
Total					896

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimated burden for the information collection reflects an overall adjustment decrease of 1,844 hours and a corresponding decrease of 18 responses. Since our last request for OMB approval of the information collection, we have adjusted our estimate of the number of respondents based on actual participation in the program. We assume the average burden required for the respective reporting and recordkeeping activities for both initial and continued participation in the program remain constant.

Dated: August 7, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023-17150 Filed: 8/9/2023 8:45 am; Publication Date: 8/10/2023]